

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s): Fuisz et al.

Examiner: Vakili, Zohreh

Application No.: 10/730,347

Group Art Unit: 1614

Filed: December 5, 2003

Docket: 1199-21

For: THIN FILM DELIVERY
SYSTEMS FOR VOLATILE
DECONGESTANTS

Dated: April 14, 2008

Confirmation No.: 1795

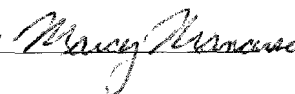
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Dated: April 14, 2008

Signature: Marcy Mancuso/



STATEMENT IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

In support of the concurrently-filed Notice of Appeal and Pre-Appeal Brief Request for Review, please reconsider the patentability of the claims of the above-identified application in view of the following Remarks. A petition for a one-month extension of time is being filed concurrently herewith. Accordingly, as April 13, 2008 falls on a Sunday, this response is timely filed on April 14, 2008, with a one-month extension of time.

Claims 1-17 and 21-33 are currently pending in this application. Claims 18-20 have been canceled. Reconsideration of the application is respectfully requested.

Claims 1, 13-19 and 30-33 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 6,596,298 to Leung et al. (hereinafter "Leung") in view of U.S. Patent No. 5,846,557 to Eisenstadt et al. (hereinafter "Eisenstadt"), U.S. Patent No. 4,980,169 to Oppenheimer et al. (hereinafter "Oppenheimer"), U.S. Patent No. 5,560,921 to Damani et al. (hereinafter "Damani") and U.S. Patent No. 6,395,299 to Babich et al. (hereinafter "Babich"). This rejection is respectfully traversed on the grounds that the art cannot be combined to form a *prima facie* case of obviousness, as required for a proper Section 103 rejection.

The Examiner asserts that Leung teaches edible films made from film forming polymers such as pullulan. According to the Examiner, Leung discloses the use of menthol and eucalyptus oils in such films. Leung, however, does not disclose or suggest the use of polydextrose in a water-soluble film forming matrix in edible films, nor does Leung disclose or suggest the use of menthol crystals in edible films. The Examiner acknowledges that Leung fails to teach the use of polydextrose in film.

For such disclosure, the Examiner points to two secondary references, Eisenstadt and Oppenheimer. First, the Examiner explains that Eisenstadt "pertains to chewing gum compositions containing cough suppressing agents." (Office Action, at page 6). According to the Examiner, the chewing gums may include decongestants and flavor agents, such as eucalyptus oil. The Examiner further asserts that Eisenstadt teaches the inclusion of polydextrose in its chewing gums as a bulking agent.

Second, the Examiner asserts that Oppenheimer relates to "medicinal tablets which deliver active ingredients in the oral cavity." (Office Action, at page 9). The Examiner states that Oppenheimer teaches the inclusion of menthol in its medicinal tablets, and that such menthol may be present as crystals.

In combining these references, the Examiner asserts that:

One having ordinary skill in the art would have been motivated to use the teachings of Leung et al. for the preparation of a rapidly dissolvable film which acts as a vehicle for administering a pharmaceutically active agent orally. Eisenstadt et al. teach flavorants and the bulking agent such as polydextrose in decongestants along with the teachings of Babich et al. for the packaging and enclosure of the product...

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the teachings of the above references and produce a film delivery system for volatile decongestants.

(Office Action, at pages 11-12).

The Examiner's assertions are respectfully traversed on the grounds that the Examiner has failed to establish a *prima facie* case of obviousness. This Pre-Appeal Brief specifically

addresses the rejection of independent claim 1 and dependent claim 33. In particular, this Brief primarily addresses the Leung, Eisenstadt and Oppenheimer references as cited in the rejection of the only independent claim currently pending, i.e. claim 1.

In particular, the Examiner combines the teachings of Leung, which relates to fast dissolving orally consumable films, and Eisenstadt, which relates to chewing gums. The Examiner asserts that it would have been obvious to use the bulking agent polydextrose disclosed as an optional additive in the chewing gums of Eisenstadt in the fast dissolving films of Leung. Such assertion is respectfully traversed.

Fast dissolving orally consumable films and chewing gums are entirely different forms of delivery systems. Fast dissolving films are highly water-soluble and are designed to completely and quickly dissolve within the oral cavity to rapidly deliver the actives contained therein. (See paragraph [0031] of the specification as filed). Not all materials which are highly water-soluble are capable of forming films. The films of the present invention are inherently self-supporting. This is due to the film forming capability of the highly water-soluble polydextrose material. The film, once formed, can be easily handled without a support structure or backing, thereby obviating the need for additional mechanical structures as support and permitting ease of manufacturing and dispensing. Polydextrose supplies this film forming feature, making it a useful component in the present invention. There is no teaching in the relevant prior art that polydextrose has film forming capability and hence no reason to try this material in a dosage form which requires the polydextrose to form a film.

In contrast to film dosages, chewing gums are predominantly water insoluble, made from rubber polymers, with flavors and sweeteners (saccharide bulking agents, such as sugar and polydextrose) added and released during chewing. Chewing gums are designed for extended mastication within the oral cavity. There are no water soluble bulking materials which can form a film during mastication of a chewing gum. Chewing gums are designed to slowly release the water-soluble bulking agents and flavors during mastication of the gum matrix, i.e., the mechanical action of chewing slowly leaches the water solubles, such as polydextrose into the mouth. Thus, these two delivery forms are distinctly different and require different components and technical considerations in their formation.

The Examiner's understanding of a "film bubble" is misplaced. The water-soluble bulking agents do not and cannot form a film in a chewing gum in any traditional sense of the word. As the Examiner clearly must appreciate, while rubber gum base elastomers are bubble-forming materials, the formation in the mouth of a bubble from the elastomers is completely different and very remote from the formation of edible films as claimed. The purpose of bulking agents such as polydextrose and sugar are to add body to the overall mass of the gum both in the dry state and when hydrated (during mastication), and help produce a good tasting (polydextrose has sweetness) and good textured gum product. It is clear from Eisenstadt that polydextrose is serving its traditional function as a bulking agent in the chewing gum. Moreover, not only is Eisenstadt devoid of any teaching or suggestion of polydextrose as a film former, it cannot function in this role in a chewing gum. Thus, it is entirely unclear how the mention of polydextrose in Eisenstadt is relevant in any way to the present invention. One of ordinary skill in the art would not look to chewing gums for insight on how to make an entirely different delivery form, one which is designed to rapidly and completely dissolve in the mouth. However, if they did seek guidance from Eisenstadt, they would fail to learn that polydextrose can create a self-supporting film dosage form. In fact, they would learn that polydextrose is a particulate filler that tends to disrupt the continuity of the chewing gum polymers during chew.

There is absolutely no teaching or suggestion in Eisenstadt to use polydextrose in a water-soluble film forming matrix. There is no formation of an edible film in chewing gum compositions, and thus, no suggestion that polydextrose can serve the function of a film former. Simply put, if one of ordinary skill in the art was looking to solve the problem of film forming, looking to Eisenstadt would provide no guidance whatsoever for the use of polydextrose. In fact, the addition of a bulking agent would suggest a greater propensity of the composition to which it is added to be disrupted by the polydextrose particulates. The Examiner has assumed that polydextrose is an obvious substitution, yet this is not the case. Moreover, none of the remaining secondary references disclose the use of polydextrose.

As such, there would be no reason for one of ordinary skill in the art to select a bulking agent, particularly polydextrose, from the chewing gum art and add it into an entirely different, rapidly dissolving film delivery system. There would be no need for a traditional bulking agent in such fast dissolving films. There also is no teaching or suggestion as to how such a bulking agent could be added into a water-soluble film forming matrix. Moreover, there is no suggestion

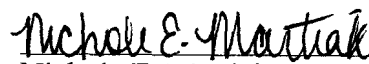
in Eisenstadt that polydextrose can serve any other function besides a bulking agent in chewing gum. Therefore, there would be no apparent reason for one of ordinary skill in the art to select the bulking agent polydextrose from the laundry listing of bulking agents disclosed in Eisenstadt for use as a film forming agent in the fast dissolving films of Leung.

In view of the above, it would not have been obvious to one of ordinary skill in the art to produce a film delivery system for volatile decongestants including polydextrose in the water-soluble film-forming matrix, as required by Appellants' present claims. Appellants respectfully submit that the claim 1, and thus all claims that depend therefrom, are patentable over Leung, Eisenstadt, Oppenheimer, Damani and Babich, each taken alone or in combination. Reconsideration and withdrawal of the Section 103 rejection is respectfully requested.

Moreover, it should be noted that the Examiner did not specifically address dependent claim 33 in any of the rejections. Claim 33 requires an enclosure for the decongestant delivery system, including an outer film obtained from a flowable water-soluble film-forming matrix, in which such outer film itself is essentially free of volatile decongestants. The Examiner has not cited any references for such disclosure of an outer film. Babich merely discloses a metal or plastic foil package, such as a blister pack. Such a metal or plastic foil blister pack is quite different from an outer film formed from a water-soluble matrix. Metal and plastic foil are not water-soluble. Therefore, Appellants submit that claim 33 additionally is patentable on this ground.

Favorable action is earnestly solicited. If there are any questions or if additional information is requested, the Examiner is respectfully requested to contact Appellants' attorney at the number listed below.

Respectfully submitted,


Nichole E. Martiak
Registration No. 55,832
Attorney for Appellants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700